

REMARKS

This amendment is responsive to the Office Action of November 14, 2007. Reconsideration and allowance of claims 1-13, 15, 17-19, and 21-33 are requested.

The Office Action

Claims 1-26 stand rejected under 35 U.S.C. § 112.

Claims 1-4, 6, 8, 9-12, 16-18, and 21-26 stand rejected under 35 U.S.C. § 102 as being anticipated by Nolan (US 5,404,877).

Claims 5, 7, 13, 15, 19, and 20 stand rejected under 35 U.S.C. § 103 as being unpatentable over Nolan in view of Toda (US 2002/00036446).

The References of Record

Nolan discloses an implanted device 5 which includes a single impedance measurement circuit 14 which has a single antenna coil 6. The antenna coil applies a source measuring current to the patient's body and measures the impedance of the current flow between the antenna system 12 and the patient's body (col. 10, lines 2-5). The measured impedance changes as organs move closer to or further away from the coil 6 (col. 10, lines 47-66).

The output of the impedance measurement circuit 14 has a single signal which can be decomposed into various components. If the coil 6 is placed adjacent and angled to interrogate the heart and lungs, from the impedance signal pulse shape and periodicity, variations attributable to heart motion, and pulmonary motion can be separated. Components which are neither attributable to cardiac or pulmonary motion or noise and can be separated to correct the heart and pulmonary signals for stray noise or patient movement in the area of the heart and lungs.

Thus, Nolan uses a single sensor which is capable of measuring multiple physiological parameters (col. 15, lines 36-39). To the extent patient motion is detected, such motion signals are artifact signals (col. 18, lines 41-43). Metabolic state would be a function of respiratory and cardiac rates.

Toda shows that piezoelectric transducers are known in the ultrasonic imaging field. It is submitted that Toda goes to enablement by showing that piezoelectric transducers are available, albeit in other fields. Toda does not disclose how to use or

provide any motivation to use a piezoelectric ultrasonic transducer in the Nolan system, much less provide an enabling disclosure as to how one would completely redesign the Nolan circuitry (which would of course be necessary) in order to function with a piezoelectric transducer.

The Present Application

The present application discloses a cardiac monitor which transmits information in an adaptive manner. For example, users of prior alarms, such as the Nolan alarm, find them annoying because they send non-critical alarms when the patient is sleeping or at other inconvenient times. By determining whether an alarm condition is critical or non-critical and by determining the patient's state of activity, such as resting or active, the presently disclosed system is able to hold non-critical alarms until the patient is awake or active. For example, if a system test determines that the battery is low but still has about 24 hours of life, the present system defers sending the low battery warning alarm to the patient until the patient is in an active state. Similarly, other non-critical alarms are held until periods of waking activity. In another example, if the biological signal and the physical activity signal indicate that a medical event has likely rendered the patient unconscious, an alarm is transmitted to a third party emergency responder.

In another embodiment, the detected physiological characteristic and the detected activity of the patient are both considered to determine whether the appearance of an alarm condition is inconsistent with the patient's current level of activity, hence that it is a false alarm. In these and other ways as described in more detail in the application, the present application alerts the patient of system errors and physiological conditions in an adaptive manner based on the detected activity level of the patient.

35 U.S.C. § 112:

The claims have been amended to correct the 35 U.S.C. § 112, second paragraph, objections raised by the Examiner. Regarding the Examiner's objection regarding "the patient" in claim 9, it is submitted that this phrase finds antecedent basis in "a patient" in lines 4 and 5 of claim 9.

The Claims are Not Anticipated by and are Patentable Over Nolan and the Other References of Record

Claim 1 calls for an activity threshold detector. While Nolan discusses that determining whether heart rate is abnormal is determined in conjunction with metabolic rates or activity, there is no suggestion in Nolan of an activity threshold detector. In Nolan if the respiratory rate is high, a high cardiac rate just shows the patient is exercising. This does not suggest a threshold.

Further, claim 1 calls for a means for adaptively controlling the communication of information about the detected biological and system functions in accordance with a level of the sensed activity as determined by the activity threshold detector. The portions of Nolan in columns 3 and 4 are used to determine whether a heart rate is normal or acceptable. The activity levels are not used for adaptively controlling the communication of information to the patient. Accordingly, it is submitted that claim 1 is not anticipated by Nolan.

New dependent claims 27-29 which set forth examples of the adaptive control distinguish more clearly over Nolan.

Claim 2 calls for a means for controlling the physical activity sensor to control a selected threshold of the activity sensor. Nolan discloses neither activity threshold nor an adjustable threshold for it.

Claim 4 calls for cardiography electrodes. Nolan measures the cardiac cycle with impedance measurements, not cardiography electrodes.

Claim 7 calls for the physical activity sensor to include a passive transducer including a piezoelectric element. Toda does not provide an enabling disclosure of how to convert the impedance monitor of Nolan into a passive piezoelectric based monitor.

Accordingly, it is submitted that claim 1 and claims 2-8 and 27-29 dependent therefrom are not anticipated by Nolan and otherwise distinguish patentably over the references of record.

Claim 9 calls for electrocardiography electrodes. Nolan discloses no electrocardiography electrodes. Rather, Nolan works on impedance measurements.

Because Nolan does not disclose electrocardiography electrodes, Nolan does not anticipate claim 9.

Claim 30 calls for the processor to control communication in accordance with an activity level of the subject and an urgency of the information. Nolan does not disclose such adaptive communication.

Claim 11 calls for a calibration means for setting a threshold of an arrhythmia threshold detector. Nolan discloses no arrhythmia threshold detector.

Claim 12 calls for the processor to save electrocardiography signals into memory, which cardiography signal are overwritten if they are below an arrhythmia threshold and saved if they are above it. Nolan includes no such storage format.

Accordingly, it is submitted that claim 9 and claims 10-15, 17, and 30 dependent therefrom are not anticipated by Nolan and otherwise distinguish patentably over the references of record.

Claim 18 has been amended only to address potential antecedent basis issues and not to change its scope. Claim 18 calls for sensing a physical activity level and comparing it to a present threshold. Nolan does not determine whether physical activity exceeds a threshold.

Claim 18 further calls for generating an error system based on the system error and transmitting such error signal to the patient if the physical activity of the patient exceeds the pre-set threshold. Nolan makes no suggestion of conditioning the transmission of the error signal based on physical activity of the patient exceeding a pre-set threshold. Accordingly, it is submitted that claim 18 is not anticipated by Nolan.

Claim 21 calls for electrocardiography electrodes. Nolan does not disclose electrocardiography electrodes.

Claim 22 calls for conditioning the communication of an arrhythmia event based on the activity level of the patient. Nolan does not disclose or fairly suggest communicating or not communicating arrhythmia events based on an activity level of the patient.

Accordingly, it is submitted that claim 18 and claims 19 and 21-22 dependent therefrom are not anticipated by Nolan and distinguish patentable over the references of record.

Claim 23 calls for transmitting an alert signal if the patient is active and inhibiting its transmission if the patient is at rest. Nolan does not disclose nor fairly suggest transmitting or not transmitting an alert signal based on whether the patient is active or at rest. Accordingly, it is submitted that claim 23 is not anticipated by Nolan.

New claims 31-33 further clarify the method to refine the conditions under which the alert signals are transmitted and not transmitted. Because these conditions are not disclosed or fairly suggested by Nolan, it is submitted that claims 31-33 are not anticipated by and distinguish yet more clearly over Nolan.

Claim 24 calls for an alarm system that produces at least two different types of alarms based on (1) the biological signal alarm condition and (2) the physical activity of the patient. Nolan does not disclose selecting and producing one of two (or more) alarms based on these two parameters. Accordingly, it is submitted that claim 24 is not anticipated by Nolan.

Claim 25 further adds a system monitor which detects systematic malfunctions and classifies them as critical or non-critical. The alarm system bases the type of alarm on the classification of the detected system malfunctions. Nolan does not classify system malfunctions as critical and non-critical, much less communicate a type of alarm based on such classification.

Claim 26 calls for determining whether a patient is unconscious from the detected biological signal and the detected physiological signal. Nolan does not suggest determining whether the patient is unconscious, much less making the determination based on these two factors. Accordingly, it is submitted that claim 26 is not anticipated by Nolan.

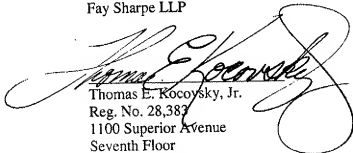
CONCLUSION

For the reasons set forth above, it is submitted that all claims distinguish patentably over the references of record and meet all statutory requirements. An early allowance of claims 1-13, 15, 17-19, and 21-33 is requested.

In the event the Examiner considers personal contact advantageous to the disposition of this case, she is requested to telephone Thomas Kocovsky at (216) 861-5582.

Respectfully submitted,

Fay Sharpe LLP

A large, stylized handwritten signature in black ink, which appears to read "Thomas E. Kocovsky, Jr.", is written over the printed name and address.

Thomas E. Kocovsky, Jr.
Reg. No. 28,383
1100 Superior Avenue
Seventh Floor
Cleveland, OH 44114-2579
(216) 861-5582